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Lifestyle modification intervention for overweight and obese Hispanic pregnant women: Development, implementation, lessons learned and future applications

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ABSTRACT

Objectives: To describe the development, implementation and lessons learned of lifestyle intervention to promote appropriate gestational weight gain among Hispanic pregnant women.
Design: The intervention was informed by an empowerment oriented theoretical framework, and targeted women in the Pregnancy and Early Life Improvement Study.
Methods: The nutrition component consisted of recommendations for total calories, food quantity and improving carbohydrate and fat quality. We provided brown rice, omega-3 rich vegetable oil and spread, and water monthly. The physical activity focused on limiting sedentary behavior and promoting regular movement. The intervention was delivered through individual and group sessions and phone calls. Participants set their own goals, which were closely monitored. The intervention was evaluated extracting data from participant's record (attendance, goals, and challenges) and using a questionnaire.
Results: Participants were from underserved communities with economic, time, cultural and social barriers for engaging in lifestyle interventions. Modifications were done to facilitate participation, such as coordinating sessions with prenatal appointments and reducing group size and duration of sessions. Weekly text messages were added to reinforce the intervention. The main goal chosen by participants was reduction of sweetened beverages. The greatest challenges were replacing white rice with brown rice and improving physical activity. Participants suggested conducting sessions near their community and using social media as a motivation tool. Main outcomes results will be published elsewhere.
Conclusion: We identified barriers to delivering the lifestyle intervention, mainly related to group session's participation. Sessions should be conducted in the community, using text messages and social media as reinforcement.
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1. Introduction

Pre-pregnancy obesity, which is a risk factor for gestational diabetes (GDM) and pre-eclampsia, is increasing in Hispanic women [5]. The attributable fraction of GDM to overweight or

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obesity is 44.2% among Hispanic women and is higher only among non-Hispanic Black women (51.2%) and American Indian (57.8%) women [11]. Although Hispanic women have a lower incidence of gestational hypertension (1.6%) compared to non-Hispanic Caucasian women (8.5%), Hispanic women with gestational hypertension are more likely to develop pre-eclampsia than non-Hispanic Caucasian women [25].

Despite several lifestyle intervention trials to prevent excessive gestational weight gain [2,6–8,12,15,17–19,24] most have resulted in small or no effects on preventing excessive gestational weight gain among overweight or obese women [3,26]. This may be due to the fact that most studies are of low to medium quality and with large differences in how outcomes are assessed [3,26]. In addition, interventions designed specifically for Hispanic pregnant women are lacking.

A lifestyle intervention was designed for overweight/obese participants in the Pregnancy and Early Lifestyle Improvement Study (PEARLS). PEARLS is a randomized controlled trial to investigate the impact of a lifestyle intervention delivered within an empowerment framework on gestational weight gain, and metabolic health and weight of the mothers and their offspring. PEARLS is part of The Lifestyle Interventions for Expectant Moms (LIFE-Moms) consortium, a collaboration between seven clinical centers, a Research Coordinating Unit, and the NIH sponsoring Institutes and Centers. Each clinical center conducts a separate trial with specific core measures, procedures, and eligibility criteria consistent across all trials allowing data to be combined and/or compared easily thereby maximizing the value of the consortium as a whole. The goals of the consortium are to determine whether various behavioral and lifestyle interventions designed to control weight gain in overweight and obese pregnant women will 1) reduce the risk of excessive gestational weight gain, 2) reduce the risk of adverse maternal and neonatal outcomes, and 3) reduce the risk of obesity in their offspring [20]. Briefly, PEARLS was conducted among overweight/obese women who were willing to receive their prenatal care at the University Hospital in San Juan, Puerto Rico. The planned sample size of 200 participants was based on a 25% reduction in inappropriate weight gain in the intervention arm with a power of 80%, assuming a two-sided alpha of 0.05 and 5% attrition rate (from miscarriage, stillbirth or loss to follow up). A total of 31 participants were randomized of the planned sample size of 200 before recruitment was stopped by NIH at 15 months based on recommendations of the LIFE-Moms Data Safety Monitoring Board due to the projected unlikelihood of accruing the target sample size within the time period allowed (32 months). Recruitment was slow because our study was originally designed to enroll participants presenting before 20 weeks of pregnancy, as our recruitment center was a referral hospital where women present later. As part of the decisions to harmonize the procedures across the different studies, the enrollment at all Life-Moms consortium study sites was required to be completed within 16 weeks of pregnancy. Although we made substantial changes in our recruitment to adapt to this core criterion, we still had a slower initial recruitment than originally planned.

The objectives of this paper are: (a) to describe the development and implementation of the pre-partum component of a lifestyle intervention that targeted Hispanic pregnant women and aimed to achieve appropriate gestational weight gain and improvement in maternal outcomes, and (b) to share lessons learned from implementing this lifestyle intervention. Main outcomes results will be published elsewhere.

2. Methods

2.1. Theoretical model

The lifestyle intervention was delivered within an empowerment theoretical framework based on the Health Self-Empowerment Theory [22]. This theory proposes that individuals can take charge of their own health by engaging in healthy behaviors regardless of social conditions that may undermine healthy living. It asserts that achieving and sustaining healthy eating and physical activity behaviors, called health-smart behaviors, requires health motivation, health self-efficacy, self-praise, health knowledge and health responsibility, and use of coping skills to manage emotions that could impact one's health. For our intervention, we followed the principles of the Health Empowerment-Focused Health-Smart Behavior Program [23]. Briefly, this program consists of first assessing each participant's motivators of and barriers to healthy behaviors called health-smart behaviors [22]. The results are then used to inform individualized coaching to set health-smart goals and identify strategies for attaining these goals and to help inform group discussions in which participants share strategies for achieving goals across participants. The program also uses visual learning tools and a written resource guide that present strategies to overcome barriers to health-smart behaviors.

2.2. Intervention design

Participants were randomized to an intervention arm or control (usual care) arm. The intervention had two components: nutrition and physical activity.

2.2.1. Nutrition component

The primary focuses of the nutritional intervention were on total calories and improving carbohydrate quality [16]. We provided clear individualized guidelines for food quantity and total calories for different phases during pregnancy to ensure adequate weight gain [9]. Additional components of the intervention included improving dietary fat quality, reducing salt and replacing red meat with low-mercury fish, nuts and beans [16]. Also, the intervention encouraged the use of prenatal multivitamin supplements as prescribed by the participant's obstetrician. To support and facilitate these changes, we provided the following items at no cost to the participants on a monthly basis: 2 lb of brown rice to use 3 times per week, 2 boxes of multigrain grain pasta, some bottles of water (mainly for motivation), a re-usable water bottle with the PEARLS logo (once), and a bottle of vegetable oil and a bottle of vegetable oil spread, both rich in omega-3 fatty acids, for daily cooking or in replacement of regular butter/margarine.

2.2.2. Physical activity component

The primary focus of this component was to increase movement and reduce sedentary time. Participants were encouraged to set a goal for a daily physical activity/exercise routine considered safe during pregnancy, according to the American Congress of Obstetrics and Gynecology [1], such as low impact aerobics and Latin dance. In addition, participants were encouraged to increase non-exercise activity thermogenesis (NEAT) by promoting regular movement and encouraging specific behaviors such as standing, walking, parking the car on the outermost side of the parking lot from one's destination, self-packing groceries, taking stairs instead of the elevator, washing dishes by hand, etc. [13,14]. For reducing sedentary periods, we recommended minimizing the duration of bouts of sitting or lying behavior during waking hours, and interrupting periods of sitting time with short bouts (2–5 min) of activity such as standing or walking.

2.3. Development of the intervention components

The intervention team was composed of nutrition and physical activity experts. Registered dietitians were trained as the lifestyle interventionists to deliver all aspects of the intervention.

The lifestyle intervention consisted of two individual visits, six group sessions and six follow up phone calls. For each session, a manual of operation was developed with scripts, goals sheet (to be completed by participants), upcoming topics to be discussed, instructions for games and exercise bouts, outline of required materials, recipes for foods to be prepared, short questionnaires to be completed, and other activities to be followed at each session. All intervention sessions were conducted on the Puerto Rico Medical Center.

2.3.1. First individual visit (1–2 weeks after randomization)

At this visit, the interventionist explained the individualized components of the intervention, starting with the caloric plan tailored for each participant based on the Institute of Medicine (IOM) energy recommendations for pregnancy [9] and recommendations on how to incorporate the foods provided with particular consideration on the participant's food preferences. Interventionist reviewed the 24-h food recall completed at baseline [4]and areas for improvement based on the key components for improving diet quality were identified. Also, the concept of NEAT and how to add additional movement to daily routines was explained. For this, we reviewed the results from the accelerometer worn by each participant at baseline to identify periods of greater sedentary activity [the accelerometer assessed physical activity in all participants, but for the intervention group, it was also used to provide feedback]. We recommended safe physical activities to do during pregnancy as per ACOG [1], such as engaging in low-impact aerobic exercise, dance, yoga for pregnancy, and striving to walk 8000 steps per day. We guided participants in choosing two nutrition goals and one physical activity goal from the 10 key messages (see Appendix 1)—goals that were written into a contract and signed by the participant. To help with the physical activity goal, we provided a pedometer and a daily physical activity log for self-monitoring, which were reviewed during subsequent sessions. In addition, we provided a weight gain-monitoring chart for participants to monitor their weight, as obtained from their regular monthly prenatal visits. We suggested the ranges for appropriate weight gain following the Institute of Medicine guidelines [10]. All of these instructions were provided as handouts. Lastly, participants were asked to complete the Motivators of and Barriers to Health-Smart Behaviors Inventory [22], which would be used in subsequent sessions to identify barriers to their goals and strategies to overcome these barriers.

2.3.2. Second individual visit (~27 weeks gestation)

At this visit we assessed each participant's progress and discussed areas for improvement. Long-term goals were revised and new ones were set if the participant met the previous goal. Results from the Motivators of and Barriers to Health-Smart Behaviors Inventory were discussed. After identifying specific motivators of and barriers to the achievement of goal behaviors, both the interventionist and the participant identified strategies to overcome these.

2.3.3. Group sessions

Sessions started 1–2 weeks after randomization and were conducted every 2 weeks. Each session was designed to last 2 h and started 2 weeks after the first individual visit. The sessions included hands-on activities and followed a pre-specified order. Specifically, group sessions focused on: (1) replacing sugar-sweetened beverages with healthy options, such as water, skim milk, diluted 100% fruit juices and coconut water; (2) replacing white rice with brown rice and increasing the bean to rice ratio (which is part of the local diet); (3) replacing other refined carbohydrates sources with their whole grain equivalents; (4) substituting saturated and trans fat with healthy options; (5) reducing salt and replacing red meat with low-mercury fish, nuts and beans; and (6) breastfeeding.

Each group session was divided in four areas:

(1) Providing key nutrition information for adequate weight gain during pregnancy as established by the IOM [9]. We developed diverse activities, given the different levels of education and attention among study participants. We focused on interactive activities that promote group work and support, such as group discussion, use of audiovisuals, demonstrations, brainstorming and problem solving exercises.
(2) Performing cooking demonstrations using healthy recipes (about 30 min). Participants were encouraged to taste the prepared foods and to suggest other ways for preparing them for the next session. We also encouraged women to experiment at home with new recipes and to share them with the group.
(3) Incorporating physical activity (every 30 min). Activity breaks starting with a 5-min stretch routine, followed by different activities were incorporated in all the sessions. Examples of these activities were: use of resistance bands, yoga, dance, steps aerobics, weight ball toss and a short walk around campus. In the activity breaks we also integrated nutritional information with fun games that promoted frequent standing and movement.
(4) Assessing difficulties and barriers and setting goals for the next group session. For this, we asked participants about their challenges, difficulties and/or barriers for meeting the short-term goals set during the previous session. We held group problem solving sessions to assess ways of overcoming such difficulties and barriers. Goals were set as a group and assessed in subsequent sessions.

2.3.4. Monthly telephone follow-ups

Calls were scheduled every month (30 min duration) to monitor: (1) weight gain, (2) food intake and (3) physical activity. We designed Excel worksheets to track these components:

(1) Short food frequency questionnaire (FFQ). It assessed progress with the key aspects of the intervention using colors to reflect changes made in comparison to baseline and the previous month. If the change was positive (i.e. decrease in consumption of sugary beverages), it was automatically highlighted in green; if there was no change, it was highlighted in yellow and if the change was negative (e.g., decrease in fruit intake), it was highlighted in red. This monitoring tool provided immediate feedback (see Appendix 2).
(2) Physical activity progress. The interventionists asked participants to report the number of days they completed the log and the number of steps recorded on the pedometer. This was compared with their individual goal set at the first individual visit, and the percent of achievement was calculated. Also, data from the accelerometer was periodically reviewed to provide feedback to the participant on how to decrease sedentary time.
(3) Weight gain tracking. Participants reported their last weight in their weight gain-monitoring chart. This value was inserted in the tracker and their weight gain was graphed using the recommended weight range according to the IOM [9].

Recommendations were provided to each participant based on the results of the weight gain tracker, the short FFQ and physical

activity progress. We created three recommendation scenarios: (1) if weight gain was above the recommendation, we reviewed areas for improvement, reinforced the key messages and established new goals; (2) if weight gain was below the recommendation, we assessed common pregnancy symptoms (i.e., vomiting and nausea), reviewed total food intake and assessed areas for improvement; (3) if weight gain was consistent with recommended weight, praise was given and any aspects of the monitored behaviors and outcomes were addressed as necessary.

A record was also created to record participant's attendance/participation to sessions/calls, to record goals, motivators and challenges, to record progress from the short phone FFQ, physical activity log and weight gain tracker, and to record feedback provided to participants during the study.

2.4. Development of the physical activity video

Most participants were from low socio-economic communities with limited recreational resources availability and lack of security to engage in outdoor activities. In addition, there are very limited available instructional exercise videos for pregnant woman in Spanish. Therefore, to reinforce the intervention, we developed a culturally appropriate video with various activities by consulting with specialists in physical activity, reviewing the relevant literature, and considering available exercise videos for pregnant woman. All activities included in our video were approved by the study supervising obstetricians.

The video provided ways to support participants' engagement in physical activity at home by including five sessions of 5–10 min each with low impact, easy to do exercises, such as stretching exercises, aerobics with resistance training, belly dance, Latin dances, and basic yoga poses and respiration techniques (performed by a certified pregnancy yoga instructor). Pregnant women from the community at different stages of pregnancy were invited to voluntarily participate in the video as motivators and as examples of exercise variations depending on the pregnancy stage. The video was produced, edited and reproduced by the Center for Learning Technology and Support of the University of Puerto Rico - Medical Sciences Campus.

2.5. Development of the resource guide

To reinforce and complement the intervention, we also developed a printed guide. Specifically, the resource guide provided information that participants may have missed as a result of being late or because of not hearing or not understanding what was imparted on a topic by the interventionist. We used the Health-Smart Behavior Resource Guide developed by Ref. [21] as a model to develop the PEARLS Resource Guide.

The PEARLS Resource Guide included 11 sections. Each section had six to eight handouts, which were organized following the order of the topics discussed in the group sessions. These handouts were prepared taking into consideration different levels of literacy, the target population, and the latest research evidence for each session/topic. We included the following handouts from the Spanish version of Tucker's Health-Smart Behavior Resource Guide: decreasing time in front of TV, healthy snacks list, cooking methods, how to control stress, sadness and anger, and healthy fast food options. A sheet with the 10 key messages of the intervention was designed to guide participants during this process (see Supplemental material).

This guide also included the goals sheet, the physical activity diary, the weight gain chart, the calendar for sessions and an individual healthy meal plan with meal substitutions listed.

3. Discussion

3.1. Implementation, modifications, and lessons learned

3.1.1. Approach for improving carbohydrate quality

When evaluating results from the short FFQ performed in the monthly calls, we found that the easiest behavior perceived by participants was reduction in sweetened beverages intake and this was the main goal set by most of them. However, most participants found it difficult to change from eating white rice to eating brown rice, as eating brown rice was not accepted by other family members at home. Furthermore, the participants found it hard to cook brown rice, even with the cooking demonstrations and the recipes provided. The FFQ also showed that participants did not increase vegetable intake. Therefore, to help participants improve carbohydrate quality, we encouraged participants to replace rice with starchy vegetables lower in glycemic index, such as green plantains and other local crops.

3.1.2. Adjustment in sessions

- Individual sessions: Although attendance to the 1st visit was 100%, the attendance was 87% for the 2nd visit. In 45% of the cases, this visit had to be done in coordination with their prenatal routine visit. It took about 2–3 attempts to schedule this individual visit with the participant, as cancellations or absences were frequent.
- Group sessions: On average, 64% (30–86%) attended the group sessions with the largest group composed of 5 participants. This component was the one with the greatest challenges. One challenge was the low volume of participants recruited at the same time with a similar gestational age to start a group, as the group sessions were designed to follow a pre-specified order. Also, it was difficult to coordinate sessions among participants due to time restrains, other commitments (work or other children) and lack of transportation. Most participants requested to schedule these sessions the same day of their prenatal routine appointment; this was only possible for a small group as the clinical appointments were outside of our control. Some women were late or did not make it because of long waiting times or delays in the clinical setting. Most group sessions were re-scheduled several times (3–4 times on average) and most sessions were conducted with only one participant in 71% of the sessions, two participants in 18% of the sessions and with 3 or more participants in only 11% of the sessions. This situation resulted in re-scheduling many small sessions to accommodate all participants. Also, sessions were shortened due to time constraints by participants and only 2–3 out of the 4 physical activities scheduled were actually done. The short walks planned were not conducted in 75% of the sessions and the cooking sessions were shortened by showing the food preparation using photos or only tasting the food with a verbal description of the recipe. The goals intended to be established at the end of the session as a group was done individually, due to the smaller groups.

3.1.3. Addition of text messages

We learned early on from our interactions with participants that they had smartphones and that text messaging and the use of social media were tools interventionists could use to contact them. We took advantage of this and developed a list of short messages focused on reinforcing the intervention and on providing coaching and motivational messages. We implemented this within two months from starting the study for all participants. These text

messages were sent every week and were in accordance with the topics discussed and the participants' gestational week. However, reviewing the participant's record, we noticed frequent service disconnection for lack of payment of their pre-paid phones. Because most of the participants were very active in the social media such as Facebook, WhatsApp and Google Plus, we also sent messages to participants via these modalities. For the few participants (1–2) who were not able to receive text messages or did not own a cellphone, messages were sent by regular mail. A reviewed protocol was submitted and approved by the IRB for these changes.

3.1.4. Adjustment in physical activity feedback

The most common goal set by participants for physical activity was to perform any kind of physical activity 3 times per week, but this goal posed the greatest challenge. Providing feedback was also a challenge as the rate of completion of the daily physical activity logs was low (only 9% completed at least 50%). To address this issue, we changed the logs to a calendar monitoring system with a simple mark (X) and a happy or sad face (see Appendix 3). Although we intended to provide feedback in real-time from the accelerometer's data, this was not possible because participant's were delayed in returning their accelerometers. Therefore, physical activity feedback during the monthly calls relied mostly on participants' verbal answer to the question regarding the number of times per week they performed any activity.

3.1.5. Motivators and barriers inventory

As mentioned above, this inventory helped individualize the intervention. A total of 8 (53%) out of 15 participants in the intervention group completed this questionnaire. Although the number of reports was low for the group, the instrument was of value to provide feedback in their monthly calls; additional efforts to increase completion would be warranted in future studies. The main motivators reported by participants for consuming healthy drinks were medical and health issues (63%) and preference (25%), while the main barriers were social influences (50%) and availability of healthy drinks (25%). For consuming healthy foods and snacks, the main motivators were health benefits (50%) and availability (50%) of such foods, while the main barriers were lack of self-control (63%) and availability (25%). The main motivators for engaging in physical activities were medical and health issues (38%) and general commitment (38%) while the main barriers were self-consciousness (50%) and limited environment support (38%). The identified motivators and barriers of these healthy behaviors were discussed at all the intervention sessions. Other barriers reported by participants not included in this inventory were related to partners' support, with some being supportive but others refused to taste the foods provided.

3.2. Evaluation of the intervention

We designed a questionnaire to evaluate the participant's experience with the intervention (see Appendix 4). This was completed by telephone at the end of the study and analyzed descriptively. This form included a Likert Scale for participants to rate how much they liked or perceived the utility of each component and tool used. Open-ended questions were also included for participants to provide suggestions and comments regarding the intervention. Evaluation data were gathered from only five participants (as the others could not be reached or did not have time to complete it), which greatly limits generalizability of these data. The evaluation results were as follows:

3.2.1. Sessions

All participants reported that duration and number of sessions, information discussed, physical activities done, and recipes demonstrated were good or excellent. They suggested that in future studies we should conduct these sessions in community centers or clinics (such as in WIC clinics), churches and shopping centers. Participants also suggested having trips to the supermarket to learn about healthy food choices while shopping, increasing the monetary incentive and including more toys and baby products as gifts.

3.2.2. Phone calls and text messages

All participants reported that the number, duration and information discussed during the follow up phone calls was either good or excellent. Also, all reported that the frequency and utility of the weekly text messages was either good or excellent. Participants proposed the use of social media to share photos, status, videos and recipe demonstrations.

3.2.3. Educational materials provided

All participants reported that the PEARLS's guide was excellent, and the average use of this guide was at least 8 times during the study. All participants reported that the physical activity video was excellent, with an average use of 3 times during the study. However, 3 participants reported that the pedometer provided was not useful mainly because they forgot to wear it.

3.2.4. Food products provided

All participants reported eating the brown rice about once per week. They suggested involving their family in the tasting demonstrations to increase acceptability at home, as well as providing more recipes. The whole grain pasta was consumed about 2–3 times per month while the vegetable oil and vegetable oil spread was used almost daily.

3.3. Future applications and conclusions

This study helped to identify barriers in developing and implementing effective ways of intervening during pregnancy. Participant feedback is essential to achieve a successful implementation of a lifestyle intervention during pregnancy. It is also important to involve key stakeholders, such as potential participants, medical care providers and family members in the planning of these interventions.

Several key issues should be taken into consideration in future interventions. Individual sessions and provision of healthier food items proved to be useful ways to deliver intervention contents. In addition, use of text messages were highly rated as a communication tool and could be useful in reinforcing interventions. Social media could also be used for this, which would also allow to share recipes and tips for making healthy changes, and to enable support among participants. These social media venues could also be used to show short videos that demonstrate cooking healthy foods using provided recipes. However, intervention group sessions should be limited in future studies working with similar groups, as these were very difficult to schedule due to several reasons. Future studies could provide transportation and/or childcare to overcome some of the barriers to attending intervention sessions. If group sessions are included, these should be conducted at community sites such as WIC clinics, schools or churches, as these sites allow easy access to intervention sessions. Additionally, group sessions ideally should be done in a way that allows participants to join any group and to make-up missed sessions. Other strategies to improve attendance to group sessions should be evaluated, such as inviting other family members or other community members to enhance support.

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Conflicts of interest

None.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.conctc.2016.05.004.

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